### Clinical Trial Management Systems Teleconference

| Date, Time & Location: | June 8, 2004; 12:00-1:00 PM EDT; Teleconference | |
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| **Attendees:** | **Center** | **Attendee** |
| | CARRA | Diane Paul |
| | Case Western | Robert Lanese |
| | City of Hope | Joyce Niland |
| | | Hemant Shah |
| | Duke | Pearl Seo |
| | First Genetic Trust | Aris Floratos |
| | Fox Chase Cancer Center | Michael Bookman |
| | Georgetown | Jieping Li |
| | Mayo Clinic | Sharon Elcombe |
| | Northwestern | Warren Kibbe |
| | OHSU | Lara Fournier |
| | Rosell Park | James Kepner |
| | | Joyce Yaskel |
| | UCSF | Teri Melese |
| | University of Iowa | Terry Braun |
| | | Jill Kuennen |
| | UC Irvine | Andrea Hwang |
| | University of Minnesota | Barry Brown |
| | | Don Connelly |
| | University of Ohio | Tahsin Kurc |
| | University of Penn | David Fenstermacher |
| | University of Pittsburgh | Mike Becich |
| | | Doug Fridsma |
| | University of Wisconsin | Jane Wegenke |
| | Vanderbilt | Sorena Nadaf |
| | Yale | Charles Lu |
| | | Prakash Nadkarni |
| | | Scot Finley |
| | NCI | Ken Buetow |
| | | Christo Andonyadis |
| | Booz Allen Hamilton | Chalk Dawson |
| | | Arumani Manisundaram |
| | | Davis Bu |
| **Contracts Update:** | • A productive contracts meeting was held and was open to all Cancer Center Participants | |
| | • Modifications to the contract are being made where possible | |
| | • GovWorks has been contacted to clarify where flexibility is possible, and feedback will hopefully be received some time this week | |
| | • A revised contract will be sent out after this feedback is received | |
| | • Statement of works are being finalized, and will be issued shortly after contracts are signed | |
| **Recommendations from the Strategic Working Group:** | • The Strategic Working Group has distributed recommendation, including: | |
| | • Request the Architecture Working Group develop a document incorporating principles and frameworks underlying the caBIG initiative | |
| | • Request the Vocabularies Working Group to develop CDE libraries and rationalize them so collaborative work can commence | |
| | • Request the Strategic Working Group form a subcommittee to stay | |

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| | abreast of global issues within the caBIG community, intellectual property, and expectation management on behalf of the Cancer Center Directors and the NCI |
| | • Request all domain Working Groups to develop "use cases" leading to functional specifications for the caBIG applications pertinent to their areas. Strategic Working Group will be tasked with harmonizing and developing overarching use cases and functional documents for the environment in toto. |
| | • Request all institutions within the caBIG community having current applications intended for incorporation into the caBIG framework to develop object models of their current system and be prepared to share them with the caBIG working teams as needed. |
| | • Request all domain Working Groups to adopt an approach of rapid prototyping and production of early testable code. |
| **Special Interest Groups:** | • SIG leads have been chosen on the basis of:<br>    o A particular expertise in the area (e.g. already a develop in the area)<br>    o Spreading of the workload around funded participants<br><br>• Participation in these SIGS follows open model for caBIG, but size must be kept at manageable levels<br><br>• Focus of SIGS will be to drill down and define functionality for each area<br><br>• Forum space will be created for each area<br><br>• SIGs will be expected to provide updates at each workspace teleconference<br><br>• caBIG Compatibility SIG<br>    o Leads: UCSF (Teri Melese) and MSK (John Speakman)<br>    o Center Participants: Fox Chase Center, Pittsburgh, Oregon, Duke, Vanderbilt, City of Hope, Fred Hutchinson, Northwestern<br>    o Goal: to evaluate systems on caBIG compatibility as outlined in the upcoming caBIG compatibility document<br><br>• Financial-Billing SIG<br>    o Lead: Iowa (Jill Kuennen)<br>    o Center Participants: Wake Forest, Iowa, Georgetown, Sloan-Kettering, Wisconsin, Vanderbilt<br>    o Goal: Identify high level functionality and requirements for a financial-billing solution<br>    o Teleconference: scheduled for June 10<br><br>• Laboratory Interfaces SIG<br>    o Lead: Memorial Sloan-Kettering (John Speakman)<br>    o Center Participants: Minnesota, Wake Forest, Georgetown, Vanderbilt<br>    o Goal: Identify high level functionality and requirements for a laboratory interface solution<br><br>• Adverse Events SIG<br>    o Lead: City of Hope (Joyce Niland)<br>    o Center Participants: VA, UC Irvine, Wake Forest, Iowa, |

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| | Mayo, Sloan-Kettering, Wisconsin, Vanderbilt, UCSF<br>○ Goal: Identify user requirements for the Adverse Events module (a survey will be distributed prior to the meeting)<br>○ Teleconference: will try to meet in about a week<br><br>• CTMS/CDUS Reporting SIG<br>○ Lead: Wisconsin (Rhoda Arzoomanian)<br>○ Center Participants: Mayo, Sloan-Kettering, Wisconsin, Vanderbilt<br>○ Goal: To identify requirements for a CTMS/CDUS solution<br>○ Teleconference: June 16 at 11am central<br><br>• Structured Protocol Representation<br>○ Lead: Doug Fridsma (UPMC)<br>○ Participants: UC Irvine, Mayo, Sloan-Kettering, Vanderbilt, City of Hope<br>○ Goal: Identify user requirements for structured protocol representation<br>○ Teleconference: June 15 at noon EDT (May be moved due to conflict in schedules)<br>○ Mailing list has been created<br><br>• CDE Curation SIG<br>○ Leads: possible co-leads from COH and UPMC<br>○ Center Participants: UPMC, COH, Yale<br>○ Goal: to coordinate clinical trials CDE curation in accordance to the caBIG CDE curation governance model<br>○ Question was raised regarding whether a normalized database format for CDEs could be made available<br>   ▪ APIs are available for CDE access<br>   ▪ Coordinate with cross-cutting workspace whether other formats are needed<br>○ Discussion occurred regarding coordination with external organizations, such as Cooperative Groups (required to submit in CDE format) and the pharmaceutical industry |
| **caBIG Compatibility Document** | • Document is under final review and will be released soon<br><br>• Will be posted on website for public viewing<br><br>• Will be sent to caBIG compatibility SIG |
| **Cross-Workspace Communications** | • Strategic planning group trying to keep track of communications with external organizations<br>○ Intent is to keep caBIG wide perspective and coordinate communications across the initiative<br>○ Forms will be sent out and should be completed before contacting external organizations<br>○ Information will be shared back<br><br>• Tissue Banks Working Group is also interested in IRB issues, and an IRB SIG should coordinate with them and the Data Sharing and Intellectual Capital Working Group<br><br>• The Training Working Group is interested in standards and templates for training that may exist at Centers, and have requested that the Centers answer a short questionnaire |

**Clinical Trial Management Systems Teleconference, June 8, 2004**

| Face to Face Meeting | <ul><li>Centers that have volunteered to host: UCSF, City of Hope, Vanderbilt, University of Pittsburgh</li><li>Initial site will be the University of Pittsburgh</li><li>Tentative date is July 19-20</li><li>Possible agenda items include reports from SIGs; breakout meetings for the SIGS, Adopters, and Developers; training sessions</li><li>Centers should respond to Davis Bu with their availability on July 19-20, and with suggestions for agenda items for the meeting</li></ul> | | | |
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| **Action Items:** | **Name Responsible** | **Action Item** | **Date Due** | **Notes** |
| | Davis Bu | Distribute caBIG meeting schedule in calendar format | June 15, 2004 | |
| | SIG Leads | Establish date of first SIG teleconference | June 11, 2004 | |
| | Center Representatives | Reply to Davis Bu with availability for face to face meeting, and suggestions for the agenda | June 22, 2004 | |

**Please list below and attach Meeting Materials and Agenda (if prepared separately):**